



10-29-03

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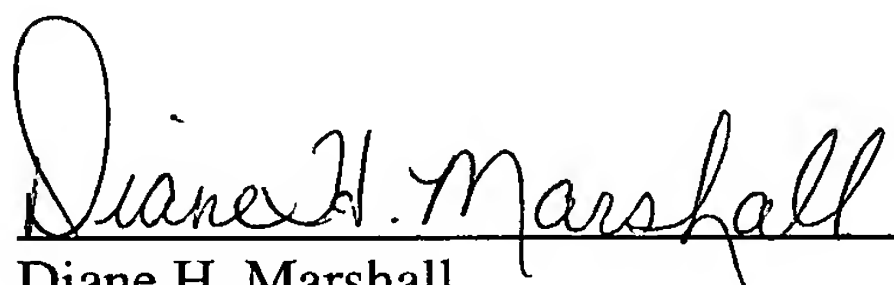
Type of Documents : Information Disclosure Statement (2 pages);
Form PTO-1449 (5 pages) and References:
13 US Patents;
10 Foreign Patents;
78 Other Documents

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Serial No. : 10/607,930

Filing Date: : June 27, 2003

I hereby certify that the documents identified above are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and are addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

 (signature)
Diane H. Marshall



PATENTS
EL 984 914 764 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	Bhatti, <i>et al.</i>	:	Examiner:	To be assigned
Serial No.:	10/607,930	:	Art Unit:	1614
Filed:	June 27, 2003	:	Docket No.:	T103 1530.1
For:	N-Aryl Diazaspiracyclic Compounds and Methods of Preparation and Use Thereof			

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants hereby voluntarily disclose the documents listed on the attached Form PTO-1449 to the Assistant Commissioner for Patents. This Information Disclosure Statement is being submitted prior to the mailing of a first Office Action on the merits of the application. Accordingly, it is believed that no fees are due. However, should any fees be due, the Patent Office is hereby authorized to charge Deposit Account No. **09-0528**. A duplicate sheet is enclosed for this purpose.

Document F3 (EP 0 417 631 A2) is a copy of the published European Patent Application (German language only). Document D78, a bibliographic printout from DELPHION research service, containing an English language abstract apparently prepared by the DERWENT company. The abstract appears to suggest that the document comprises a discussion of condensed diazepinones of the general formula I (see published European patent application for formula I), having the substituents are recited therein. The document apparently alleges that such compounds are suitable for the therapy or cholinergically related spasms and motility disturbances in the gastrointestinal tract, in the biliary tract, for the symptomatic therapy of cystitis and of spasms associated with urolithiasis, for the therapy of relative incontinence, for the symptomatic therapy of bronchial asthma and of bronchitis, and for the therapy of ischaemic heart diseases.

The document D66 (Süess, Rudolf, "Regiospezifische Reduktionen von 1,3,3-trisubstituierten Succinimiden mit Diboran," *Helv. Chim. Acta* 60: 1650-1656 (1977)), in the German language, was published with an English abstract that appears to indicate that the document discusses the regiospecific reduction of 1,3,3-trisubstituted succinimides by diborane.

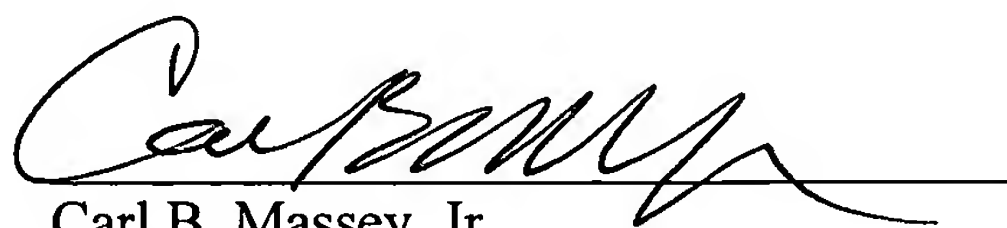
The document D67 (Sury, *et al.*, "Über Alkylenimin-Derivate. Beitrag zur Kenntnis der Diaza-spiro-undecane," *Helv. Chim. Acta* 36: 1815-1820 (1953)) in the German language, appears to indicate that the document discusses procedures for the preparation of diaza-spiro-undecanes.

Copies of one hundred one (101) documents are enclosed. Applicants further reserve the right to establish the patentability of the claimed invention over any of the listed information should they be applied as documents, and/or to prove that the cited information may not be prior art, and/or to prove that the cited information may not be enabling for the teachings they purport to offer. This statement further should not be construed as the representation that any search has been made, or that the information cited herewith is material, or that there does not exist information more material to the examination of the present Application. The Examiner is specifically requested not to rely solely on the information submitted herein. On the contrary, the Examiner is requested to conduct an independent and thorough review of all available information, and to form independent opinions as to its significance.

It is respectfully requested that the Examiner initial and return copies of the enclosed PTO-1449 and to indicate in the official file wrapper of the above-identified patent application that each item of the cited information has been considered.

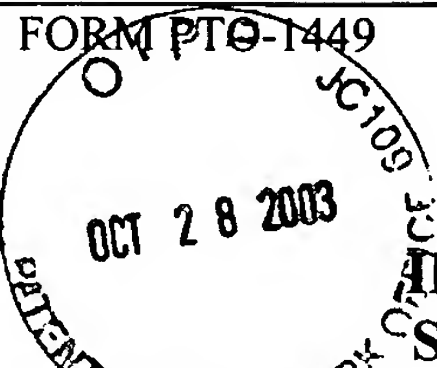
Respectfully submitted,

Date: Oct 27, 2003



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FORM PTO-1449 	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DKT NO. T103 1530.1	SERIAL NO. 10/607,930
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT Bhatti, <i>et al.</i>	
			FILING DATE 06-27-03	GROUP 1614

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CL.	SUBCL.	FILING DATE IF APPROP.
	P1	3,282,947	11/1966	Grogan, <i>et al.</i>	260	293	
	P2	4,922,901	05/1990	Brooks, <i>et al.</i>	128	203.26	
	P3	5,187,166	02/1993	Kikuchi, <i>et al.</i>	514	249	
	P4	5,583,140	12/1996	Bencherif, <i>et al.</i>	514	299	
	P5	5,597,919	01/1997	Dull, <i>et al.</i>	544	242	
	P6	5,604,231	02/1997	Smith, <i>et al.</i>	514	256	
	P7	5,616,716	04/1997	Dull, <i>et al.</i>	546	300	
	P8	5,663,356	09/1997	Ruecroft, <i>et al.</i>	546	300	
	P9	5,672,601	09/1997	Cignarella	514	249	
	P10	5,733,912	03/1998	Wasicak, <i>et al.</i>	514	253	
	P11	5,852,041	12/1998	Cosford, <i>et al.</i>	514	351	
	P12	6,022,868	02/2000	Olesen, <i>et al.</i>	514	210	
	P13	US 2003/ 0092700	05/2003	Czollner, <i>et al.</i>	514	217.01	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CL.	SUBCL	TRANSLATION	
							YES	NO
	F1	EP 0 297 858	01/1989	EP				
	F2	EP 0 360 390	03/1990	EP				
	F3	EP 0 417 631	03/1991	EP				
	F4	GB 2 295 387	05/1996	GB				
	F5	WO 94/08992	4/1994	WO				
	F6	WO 96/31475	10/1996	WO				
	F7	WO 96/40682	12/1996	WO				
	F8	WO 97/40049	10/1997	WO (See published English language related application P13 above)				
	F9	WO 98/25619	06/1998	WO				
	F10	WO 99/21834	05/1999	WO				

EXAMINER

DATE CONSIDERED

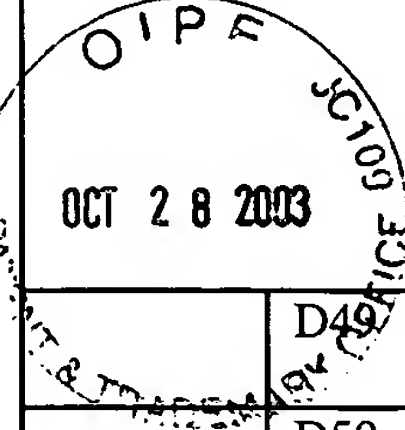
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

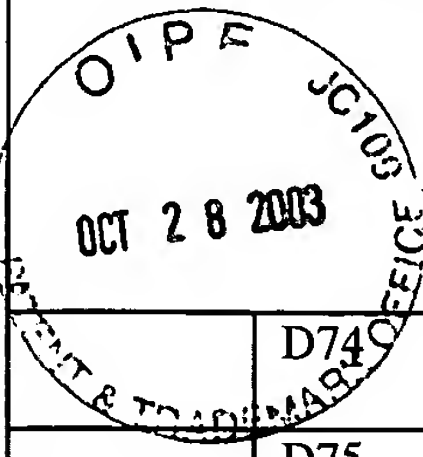
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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE OCT 28 2003 INFORMATION DISCLOSURE STATEMENT BY APPLICANT		ATTY DKT NO. T103 1530.1	SERIAL NO. 10/607,930
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OTHER DOCUMENTS (Incl. Author, Title, Date, Pertinent pages, etc.)			
D1	Abramovitch, R.A., editor, "Pyridine and Its Derivatives," Supp. Part Three, pp. 3-5, in <i>Chemistry of Heterocyclic Compounds</i> , Volume 14 (Interscience Publishers, 1974).		
D2	Adamcik, J.A., and E.J. Miklasiewicz, "Cyanoethylation. I. Weakly Basic Catalysts in the Reaction of Acrylonitrile with Active Methylene Compounds," <i>J. Org. Chem.</i> 28: 336-339 (1963).		
D3	Arneric, S., et al., "Preclinical Pharmacology of ABT-418: A Prototypical Cholinergic Channel Activator for the Potential Treatment of Alzheimer's Disease," <i>CNS Drug Rev.</i> , 1(1): 1-26 (1995).		
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D5	Bannon, A.W., et al., "Broad-Spectrum, Non-Opioid Analgesic Activity by Selective Modulation of Neuronal Nicotinic Acetylcholine Receptors," <i>Science</i> , 279: 77-81 (1998).		
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D8	Brioni, J.D., et al., "The Pharmacology of (-)-Nicotine and Novel Cholinergic Channel Modulators," <i>Adv. Pharmacol.</i> , 37: 153-215 (1997).		
D9	Burger, A., et al., "Some Derivatives of Tetrahydropyran as Potential Pharmacodynamic Agents," <i>J. Am. Chem. Soc.</i> , 72: 5512-5515 (1950).		
D10	Cheng, Y., and W.H. Prusoff, "Relationship Between the Inhibition Constant (K_i) and the Concentration of Inhibitor which Causes 50 Per Cent inhibition (I_{50}) of an Enzymatic Reaction," <i>Biochem. Pharmacol.</i> 22(23): 3099-3108 (1973).		
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D12	Ciblat, S., et al., "A new route to 2-spiropiperidines," <i>Tet. Lett.</i> , 42: 4815-4817 (2001).		
D13	Clarke, K., and K. Rothwell, "A Kinetic Study of the Effect of Substituents on the Rate of Formation of Alkylpyridinium Halides in Nitromethane Solution," <i>J. Chem. Soc.</i> , 1885-1895 (1960).		
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D16	Culbertson, T.P., et al., "Quinolone Antibacterial Agents Substituted at the 7-Position with Spiroamines. Synthesis and Structure-Activity Relationships," <i>J. Med. Chem.</i> , 33(8): 2270-2275 (1990).		
D17	Damaj, M.I., et al., "Analgesic Activity of Metanicotine, A Selective Nicotinic Agonist," <i>Society for Neuroscience</i> , 23: 669 ABSTRACT 266.9 (1997).		
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D19	Decina, P., et al., "Cigarette Smoking and Neuroleptic-Induced Parkinsonism," <i>Biol. Psychiatry</i> , 28(6): 502-508 (1990).		
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D22	Genin, M.J., et al., "Synthesis and Crystal Structure of a Peptidomimetic Containing the (R)-4.4-Spiro Lactam Type-II β -Turn Mimic," <i>J. Org. Chem.</i> , 58(8): 2334-2237 (1993).		
D23	Genin, M.J., and R.L. Johnson, "Design, Synthesis, and Conformational Analysis of a Novel Spiro-Bicyclic System as a Type II β -Turn Peptidomimetic," <i>J. Amer. Chem. Soc.</i> , 114(23): 8778-8783 (1992).		

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D24	Gibson, S., <i>et al.</i> , "Principal Components Describing Biological Activities and Molecular Diversity of Heterocyclic Aromatic Ring Fragments," <i>J. Med. Chem.</i> , 39(20): 4065-4072 (1996).		
D25	Grogan, C.H., <i>et al.</i> "Spiranes. VII. Neuroleptics Derived from Azaspiranes," <i>J. Med. Chem.</i> , 8: 62-73 (1965).		
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D28	Hansch, C., <i>et al.</i> , "The Parabolic Dependence of Drug Action upon Lipophilic Character as Revealed by a Study of Hypnotics," <i>J. Med. Chem.</i> , 11(1): 1-11 (1967).		
D29	Hansch, C., <i>et al.</i> , "A Survey of Hammett Substituent Constants and Resonance and Field Parameters," <i>Chem. Rev.</i> , 91(2): 165-195 (1991).		
D30	Hansen, M.M., <i>et al.</i> , "An Enantioselective Synthesis of Cis Perhydroisoquinoline LY235959," <i>J. Org. Chem.</i> , 63(3): 775-785 (1998).		
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D33	Hertog, H.J.D., <i>et al.</i> , "The Directive Influence of the N-Oxide Group During the Nitration of Derivatives of Pyridine N-Oxide (IV) ¹) Nitration of 3-bromo-5-methoxy- and 3,5-dimethoxy-pyridine-N-oxide ²)," <i>Recueil Trav. Chim. Pays-Bas</i> , 74(8/9): 1171-1179 (1955).		
D34	Hery, F., <i>et al.</i> , "Control of the Release of Newly Synthesized ³ H-5-Hydroxytryptamine by Nicotinic and Muscarinic Receptors in Rat Hypothalamic Slices," <i>Naunyn-Schmiedeberg's Arch. Pharmacol.</i> , 296: 91-97 (1977).		
D35	Hinds, M.G., <i>et al.</i> , "Synthesis, Conformational Properties, and Antibody Recognition of Peptides Containing β -Turn Mimetics Based on α -Alkylproline Derivatives," <i>J. Med. Chem.</i> , 34(6): 1777-1789 (1991).		
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D37	Holladay, M.W., <i>et al.</i> , "Neuronal Nicotinic Acetylcholine Receptors as Targets for Drug Discovery," <i>J. Med. Chem.</i> , 40(26): 4169-4194 (1997).		
D38	Holland, A. <i>et al.</i> , "Isothiazoles. Part IX. Isothiazolopyrimidines," <i>J. Chem. Soc.</i> , 7277-7282 (1965).		
D39	Hughes, D.L., "The Mitsunobu Reaction," <i>Org. React.</i> , 42: 335-657 (1992).		
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D41	Islam, A.M., and R.A. Raphael, "A Direct Transformation of cycloHexanones into bicyclo [5: 3: 0] Dec-7-en-9-ones," <i>J. Chem. Soc.</i> , 3151-3154 (1955).		
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D43	Lall, M.S., <i>et al.</i> , "Serine and Threonine β -Lactones: A New Class of Hepatitis A Virus 3C Cysteine Proteinase Inhibitors," <i>J. Org. Chem.</i> , 67(5): 1536-1547 (2002).		
D44	Latli, B., <i>et al.</i> , "Novel and Potent 6-Chloro-3-pyridinyl Ligands for the $\alpha 4\beta 2$ Neuronal Nicotinic Acetylcholine Receptor," <i>J. Med. Chem.</i> , 42(12): 2227-2234 (1999).		
D45	Lavand'homme, P., and J.C. Eisenach, "Sex Differences in Cholinergic Analgesia II: Differing Mechanisms in Two Models of Allodynia," <i>Anesthesiology</i> , 91(5): 1455-1461 (1999).		
D46	Lippiello, P.M., <i>et al.</i> , "RJR-2403: A Nicotinic Agonist with CNS Selectivity II. <i>In Vivo</i> Characterization," <i>J. P. E. T.</i> , 279(3): 1422-1429 (1996).		
D47	Majer, Z., <i>et al.</i> , "Synthesis and Absolute Configuration of 1,7 Diazaspiro[4,4]Nonane-2,6-Dione," <i>Coll. Czech. Chem. Comm.</i> , 47(3): 950-960 (1982).		
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	D49	Onaivi, E.S., <i>et al.</i> , "Chronic Nicotine Reverses Age-Associated Increases in Tail-Flick Latency and Anxiety in Rats," <i>Life Sciences</i> , 54(3): 193-202 (1994).			
	D50	Overberger, <i>et al.</i> , "Absolute Configuration of 2,7 Diazaspiro[4.4]nonane. A Reassignment," <i>J. Org. Chem.</i> , 46(13): 2757-2764 (1981)			
	D51	Overman, L.E., and R.M. Burk, "A Convenient Synthesis of Unsymmetrical Secondary Amines. <u>In Situ</u> Formation of Unstable Formaldehyde Imines," <i>Tet. Lett.</i> , 25(16): 1635- 1638 (1984).			
	D52	Pedersen, M.L., and D.B. Berkowitz, "Formal α -Vinylolation of Amino Acids. Use of a New Benzeneselenolate Equivalent," <i>J. Org. Chem.</i> , 58(25): 6966-6975 (1993).			
	D53	Pomerleau, O.F., <i>et al.</i> , "The Effects of Cigarette Smoking on Pain and Anxiety," <i>Addictive Behaviors</i> , 9: 265-271 (1984).			
	D54	Pullan, R.D., <i>et al.</i> "Transdermal Nicotine for Active Ulcerative Colitis," <i>New England J. Med.</i> , 330(12): 811-815 (1994).			
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	D57	Rapier, C., <i>et al.</i> , "Stereoselective Nicotine-Induced Release of Dopamine from Striatal Synaptosomes: Concentration Dependence and Repetitive Stimulation," <i>J. Neurochem.</i> , 50(4): 1123-1130 (1988).			
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	D59	Ricciardi, F.J., and P.H. Doukas, "Facile Synthesis of Styrlquinuclidines," <i>Heterocycles</i> , 24(4): 971-977 (1986).			
	D60	Rice, L.M., <i>et al.</i> , "Spiranes. V(1) A Synthetic Route to Symmetrical and Unsymmetrical 3,9-Diazaspiro [5.5] undecanes," <i>J. Het. Chem.</i> , 1(3): 125-127 (1964).			
	D61	Rowell, P.P. and D.L. Winkler, "Nicotinic Stimulation of [3 H] Acetylcholine Release from Mouse Cerebral Cortical Synaptosomes," <i>J. Neurochem.</i> , 43(6): 1593-1598 (1984).			
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	D63	Sandor, N.T., <i>et al.</i> "Effect of nicotine on dopaminergic-cholinergic interaction in the striatum," <i>Brain Res.</i> , 567: 313-316 (1991).			
	D64	Selnick, H.G., <i>et al.</i> , "Preparation and Trapping of 3-Lithium-O-Lithiophenoxide," <i>Tet. Lett.</i> , 34(13): 2043-2046 (1993).			
	D65	Smith, P.W., <i>et al.</i> , "New Spiropiperidines as Potent and Selective Non-Peptide Tachykinin NK ₂ Receptor Antagonists," <i>J. Med. Chem.</i> , 38(19): 3772-3779 (1995).			
	D66	Süess, R. and A.G. Sandoz, "Regiospezifische Reduktionen von 1,3,3-trisubstituierten Succinimiden mit Diboran," <i>Helv. Chim. Acta</i> , 60: 1650-1656 (1977).			
	D67	Sury, E., and K. Hoffmann, "Über Alkylenimin-Derivate. Beitrag zur Kenntnis der Diaza-spiro-undecane," <i>Helv. Chim. Acta</i> , 36: 1815-1820 (1953).			
	D68	Thomas, J. and D. Clough, "The Preparation and Measurement of the Surface Activity of a Series of 4-Alkyl-1,1'-Spirobipiperidinium Bromides," <i>J. Pharm. Pharmacol.</i> , 15(3): 167-177 (1963).			
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	D72	Wagaw, S. and S.L. Buchwald, "The Synthesis of Aminopyridines: A Method Employing Palladium-Catalyzed Carbon-Nitrogen Bond Formation," <i>J. Org. Chem.</i> , 61(21): 7240-7241 (1996).			
	D73	Wagner, B., <i>et al.</i> , "Does Smoking Reduce the Risk of Neuroleptic Parkinsonoids?," <i>Pharmacopsychiat.</i> , 21: 302-303 (1988).			

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 INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICANT Bhatti, <i>et al.</i>	
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	D74	Wittekind, R.R., and C. Weissman, "Synthesis of the 1,8-Diazaspiro [4.5] decane System," <i>J. Het. Chem.</i> , 9(1): 111-113 (1972).			
	D75	Williams, M., <i>et al.</i> , "Neuronal Nicotinic Acetylcholine Receptors," <i>Drug News Perspec.</i> , 7(4): 205-223 (1994).			
	D76	Zhu, J., <i>et al.</i> "Asymmetric Synthesis. 29. ¹ Preparation of 1,8-Diazaspiro{5.5} undecane Derivatives," <i>J. Org. Chem.</i> , 58(23): 6451-6456 (1993).			
	D77	Zwart, C., and J.P. Wibaut, "Chemical Behaviour of 3-Aminopyridine and of 3,5-Diaminopyridine. Syntheses of (3-Pyridyl)-Pyrazolones." <i>Recueil Trav. Chim. Pays-Bas</i> , 74(8/9): 1062-1069 (1955).			
	D78	Delphion Printout – Bibliographic Data for EP 0417 631 A2 (Document F3) shows Derwent English language abstract. Oct. 21, 2003.			
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